

EXHIBIT 21

Reed MDL Complaint, Case No. 1:13-cv-12565, Dkt. 1 (excerpt)

IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE

WAYNE A. REED, individually as husband and)
next of kin of decedent, DIANA E. REED,)
Plaintiff,)
v.)
AMERIDOSE, LLC, MEDICAL SALES) Case No.
MANAGEMENT, INC., MEDICAL SALES) JURY DEMAND
MANAGEMENT SW, INC., GDC)
PROPERTIES MANAGEMENT, LLC, ARL)
BIO PHARMA, INC. D/B/A ANALYTICAL)
RESEARCH LABORATORIES, BARRY J.)
CADDEN, GREGORY CONIGLIARO, LISA)
CONIGLIARO CADDEN, DOUGLAS)
CONIGLIARO, CARLA CONIGLIARO,)
GLENN A. CHIN, SAINT THOMAS)
OUTPATIENT NEUROSURGICAL CENTER,)
LLC, HOWELL ALLEN CLINIC A)
PROFESSIONAL CORPORATION, JOHN)
CULCLASURE, M.D., DEBRA SCHAMBERG,)
R.N., SAINT THOMAS WEST HOSPITAL)
formerly known as ST. THOMAS HOSPITAL,)
SAINT THOMAS NETWORK and SAINT)
THOMAS HEALTH,)
)
Defendants.

COMPLAINT

Plaintiff, Wayne A. Reed, individually as husband and as next of kin of his deceased wife, Diana E. Reed, for his cause of action against the defendants respectfully states to the Court as follows:

INTRODUCTION

1. This lawsuit arises as a result of a widespread outbreak of fungal meningitis over the past year that has affected people in at least 20 states and caused over 60 deaths. One of those

113. On March 24, 2005, USA Today published a front page article with the following headline: “**Safety concerns grow over pharmacy-mixed drugs.**” That article discussed growing concern over the fact that drugs produced in bulk by compounding pharmacies are not FDA approved and are not subject to the same oversight as drugs produced by pharmaceutical companies. A true and correct copy of the text from that article is attached as Exhibit B.

114. In 2006, the FDA conducted a survey of compounded drug products. They collected thirty-six samples from compounding pharmacies across the United States during unannounced visits. Twelve of the 36 samples (33%) failed analytical testing. The FDA survey concluded “poor quality compounded drugs are a serious public health concern, as improperly compounded products have been linked to grave adverse events, including deaths.” A true and correct copy of the FDA’s report titled *2006 Limited FDA Survey of Compounded Drug Products* is attached as Exhibit C.

115. In May 2007, the FDA published an article titled “The Special Risks of Pharmacy Compounding.” (Exhibit D attached). That article highlighted numerous adverse events involving compounded products. It also warned of the emergence of large scale compounding operations that were clearly operating outside of the bounds of traditional compounding practice.

116. In 2010, the FDA posted an educational video on YouTube regarding concerns over the quality of compounded drugs. That educational video is found on the World Wide Web at http://www.youtube.com/watch?v=kif_rmtIQb0.

117. On November 5, 2010, the American Society of Anesthesiologists, the American Society of Health-System Pharmacists (“ASHP”) and other medical societies published a joint report regarding drug shortages. That report included an article written by the ASHP stating as follows:

NECC. Accordingly, the Tennessee Defendants are jointly and severally liable for all harm caused by NECC's conduct.

COUNT III
NEGLIGENCE
(Against NECC Related Defendants)

196. As the designer, tester, compounder, seller, marketer and/or distributor of consumer products, the NECC Related Defendants owed a duty to Plaintiff to comply with existing standards of care, and to exercise due care, in providing a safe and quality product to Diana Reed.

197. Specifically, but without limitation:

- a. Ameridose, MSM/MSMSW, GDC, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Douglas Conigliaro, Carla Conigliaro, and Glenn Chin owed Diana Reed a duty to provide methylprednisolone acetate that was safe and free of contamination.
- b. ARL owed Diana Reed a duty to properly conduct tests to insure that the methylprednisolone acetate was safe and free of contamination.

198. Defendants breached those duties, and were otherwise negligent in their design, compounding, sale, testing, marketing, and distribution of the recalled steroid medication, which was administered to Diana Reed. The Defendants failed to exercise due care in accordance with the standard of care and skill required of, and ordinarily exercised by, a designer, compounder, tester, seller, marketer, and distributor of steroid medications, as licensed to do so by the Commonwealth of Massachusetts. The Defendants, by and through their supervisors, staff and agents engaged in designing, compounding, storing, testing, selling, marketing and distributing MPA in a negligent manner.